Liza M. Walsh
Tricia B. O'Reilly
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, NJ 07068
Telephone: (973) 535-0500
Facsimile: (973) 535-9217

Paul H. Berghoff
David M. Frischkorn
Alison J. Baldwin
MCDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606
Tel.: (312) 913-0001
Fax: (312) 913-0002

*Attorneys for Defendants*

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| NOVO NORDISK A/S,<br>Plaintiff,<br><br>v.<br><br>SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS and SANOFI-AVENTIS DEUTSCHLAND GMBH<br><br>Defendants. | Civil Action No. 07-3206 (MLC/JJH)<br><br>**EXPERT DECLARATION OF NEIL SHEEHAN** |

## I. INTRODUCTION

1. I have been retained as an expert witness in this case on behalf of Defendants sanofi-aventis U.S. LLC and Sanofi-aventis (collectively "s-a") to render an opinion as to the construction of the patent claims, the prior art, including materiality, and the invalidity of the following patent claims, which are asserted by Plaintiff Novo Nordisk A/S ("Novo") against s-a's SoloStar® pen injector:

Claims 1 and 7-26 of U.S. Patent No. 7,241,278 ("278 Patent").[1]

2. I submit this declaration in response to Novo's preliminary injunction motion and pursuant to Fed. R. Civ. P. 26(a)(2)(B), however, I reserve the right to file supplements to this declaration as this case proceeds. I have formed the opinions expressed in this declaration through my independent evaluation and analysis. If called upon to testify in this case, I can competently testify to the matters addressed in this declaration, the attachments thereto, and the materials I relied upon in rendering my opinions. I may also rebut any testimony, reports, or opinions proffered by Novo's witnesses (expert or otherwise).

### A. Summary of Opinions

3. Claims 1 and 7-26 are invalid for failure to meet the written description requirement.[2]

4. Claims 1 and 7-26 are invalid for failure to enable one of ordinary skill in the art to practice the claimed invention.

5. Claims 1 and 7-26 are invalid because Bernard Sams invented what Novo alleges its inventor invented.

---

[1] In my materiality inquiry, I have investigated whether certain items were highly material to all of the claims of the 278 Patent, not just the asserted claims.

[2] I understand that these are the only claims that Novo has asserted. However, if Novo withdraws any claims or asserts additional claims, I reserve the right to supplement this declaration.

6. Claims 1 and 7-26 are invalid as anticipated by the prior art.

7. Claims 1 and 7-26 are invalid as obvious in view of the prior art.

8. A number of items that were not presented to the United States Patent Office Examiner during the prosecution of the 278 Patent are highly material to the patentability of the claims of this patent.

**B. Qualifications**

9. I am currently self-employed as a consulting engineer in the field of medical products. A copy of my curriculum vitae, which includes, among other things, my academic credentials and my employment history, is attached to this declaration as Exhibit A1.

10. My field of expertise in this matter is medical products and devices, including medication delivery systems. This declaration is based upon my own personal knowledge, skill, experience, training, and education in my field of expertise, and upon information I have reviewed in connection with my retention as an expert witness in this matter.

11. I received my Bachelor of Science degree in Mechanical Engineering, *summa cum laude*, from Villanova University in 1968. I was the recipient of their 1993 Alumni Achievement Award for my work in the medical device field. I took graduate courses in the Department of Engineering and Applied Physics at Harvard University in 1968-1969. I also took courses in biology and organic chemistry at the University of California at Berkeley in 1974-1975.

12. I have over thirty years of experience in medical device design and development, with roles ranging from that of an individual contributor to that of a Vice President of Engineering and Manufacturing.

13. I have been directly involved in the design, development and manufacture of medical devices since 1975, both as an employee and as a consultant. I have worked extensively in the area of medication delivery systems, including intravenous ("IV") delivery systems, hemodialysis blood

lines, peritoneal dialysis catheters and connectors, syringes (safety and otherwise), liquid handing systems (especially pipettors) and other similar systems.

14. I am a named inventor on 37 patents in the medical device field covering a broad range of products, a number of which are directed at different types of medication delivery systems and components.

15. In addition, I have designed and worked with hundreds of medical devices, including syringe related products. In fact, I have contributed to the design of a complete line of safety syringes and associated components.

16. I am knowledgeable and capable of testifying regarding medication delivery systems, including pen type devices as well as the prior art devices, items, documents, and information relating to the patent-in-suit.

**C. Prior Testimony, Publications, and Compensation**

17. My qualifications and testimony as an expert in the field of medication delivery devices have been accepted in eleven different cases: seven times in court, three times in arbitration proceedings, and once before the Board of Patent Appeals and Interferences at the U.S. Patent & Trademark Office ("PTO").

18. I have testified as an expert witness, at trial or in a deposition, in several other cases within the past four years. A list of these cases is attached as Exhibit A2 to this declaration.

19. I have authored no publications within the preceding ten years.

20. My compensation for my work in this matter is $350 per hour and is not contingent upon the outcome of this litigation.

**D. Materials Considered and Reviewed**

21. In forming the opinions expressed in this Declaration, I considered and reviewed a number of documents and things, which are identified in a list attached as Exhibit A3 to this

Declaration.[3] I reserve the right to provide my opinions on other issues in this matter at the appropriate time.

**E. Person of Ordinary Skill in the Medication Delivery Device Art**

22. I have examined the issue of the relevant field of art for the patent-in-suit and the level of skill in the art at the time of the invention. The field of art appropriate for the patent-in-suit, as well as the relevant prior art, is medication delivery devices of various types, including pen type medical devices, with or without needles. This encompasses medication delivery devices that may be used for injection and/or administration, transport and/or control of medications such as insulin, growth hormone, and similar medications.[4]

[3] A list identifying each of the documents, items and things considered for my declaration, including those cited in the attached claim charts (Exhibits B1-B8) is included in Exhibit A3. Where applicable, I will refer to these prior art documents in abbreviated form in this declaration and the attached claim charts. For example, I refer to U.S. Patent 5,480,387 to Gabriel et al. as "Gabriel 387."

[4] My understanding of the field of art appropriate for the patent-in-suit is consistent with the various medication device references cited by the inventor during the prosecution of the 278 Patent in the form of Information Disclosure Statements that are part of the file history of the 278 Patent.

## II. LEGAL STANDARDS

### A. Invalidity

23. I understand that a patent claim can be invalid under the patent laws for various reasons, including, for example, anticipation or obviousness in light of the prior art, failure to satisfy the written description requirement, failure to disclose the best mode, indefiniteness, invented by another (derivation), or failure to provide an enabling disclosure. In arriving at my opinions, I have applied the following legal standards and analyses regarding patent invalidity.

#### 1. Burden of Proof

24. I understand that s-a has the burden to prove invalidity by "clear and convincing evidence." The clear and convincing evidence standard is a higher standard than the preponderance of the evidence standard, but a lower standard than the beyond a reasonable doubt standard.

25. I understand that United States patents are presumed valid because they are subject to an examination process at the PTO. Additionally, I understand the burden of proof for invalidity is the clear and convincing standard, however, I also understand that this standard is easier to meet when invalidity is based upon prior art that was not considered by the PTO. [5]

#### 2. Anticipation

26. I understand that a claim is anticipated by a prior art document or item if the prior art document or item discloses every limitation in the claim. Such a disclosure can be express (it says it or shows it), or it can be inherent (it must necessarily be there even if the reference does not say it or show it). If the claim is anticipated, the claim is invalid.

---

[5] By prior art, I include prior art references as well as prior art items and devices. I understand that if a reference, item, or device does not fall within one of the prior art definitions as outlined in the patent statute, that reference, item, or device may still be considered within the knowledge or understanding of one of ordinary skill in the art.

27. I understand that a first step in an anticipation analysis is to construe the claim, and a second step is to compare the construed claim to the prior art reference or device. A claim is anticipated if all the limitations of the claim are disclosed in the prior art.

**3. Obviousness**

28. I understand that a patent claim may be invalid for obviousness even if it is not anticipated by the prior art. I understand that a patent claim is obvious if the differences between the claimed invention and the prior art are such that the subject matter of the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was claimed. If the claim is obvious, the claim is invalid.

29. I understand that before an obviousness determination is made, the level of ordinary skill in the art must be considered, and the scope and content of the prior art must be considered, as well. I understand that to determine the scope and content of the prior art, one must determine what prior art is reasonably pertinent to the particular problem the inventor faced. I understand that prior art is reasonably pertinent if it is in the same field as the claimed invention, or is from another field that a person of ordinary skill in the art would look to in trying to solve the problem.

30. I understand that the Supreme Court recently decided a case where it rejected the doctrine that a patent claim may be obvious if the prior art would have suggested to, or motivated, one of ordinary skill in the art to combine certain prior art references to arrive at the elements of the claim. I understand now that one should look at interrelated teachings of multiple patents, the effects of demands known to the design community or present in the marketplace, and the background knowledge possessed by a person having ordinary skill in the art – all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. Further, a person of ordinary skill is a person of ordinary creativity, not an automaton. This person of ordinary creativity works in the contexts of a community of inventors and of the marketplace. The non-obviousness inquiry needs to reflect these realities within which inventions

and patents function. In order to conclude that an invention is obvious, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

31. I understand that a claim limitation using "means for" or similar language, and reciting only a function without reciting a structure for performing that function, is a "means-plus-function" limitation. I also understand that the means-plus-function limitation must be interpreted in light of the corresponding structure disclosed in the specification (or equivalents of the corresponding structure) and that such disclosed structure must perform the recited function. If this inquiry reveals that the specification does not disclose corresponding structure for performing this recited function, the claim will be invalid for failure to satisfy the definiteness requirement of the patent statute.

**4. Written Description**

32. I understand that a patent claim will be invalid for failure to meet the written description requirement if the written description does not allow one of ordinary skill in the art to discern that what has been claimed has in fact been invented. I understand that the patent must convey with reasonable clarity to those skilled in the art that, as of the filing date, the applicant was in possession of the full scope of the claimed invention as construed. I understand that one of the purposes of this requirement is to prevent a patent applicant from overreaching the scope of his or her contribution to the art.

33. I understand that a patent applicant must provide a written description of the claimed invention. I further understand that to satisfy this requirement, the original application must describe an invention in sufficient detail such that one skilled in the art can clearly conclude that the inventor was in possession of the invention as of the filing date of the original application. In other words, the patentee must provide a written description of the claimed invention such that a person of ordinary skill in the art can clearly conclude that the patentee invented what is claimed.

34. I understand that the written description should include such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. I further understand that the purpose of the written description requirement is to prevent the inventor from overreaching his invention beyond what he or she reasonably conveyed in the original disclosure.

35. I understand that the claims of a patent must particularly point out and distinctly claim the subject matter that the applicant regards as his or her invention.

**5. Enablement**

36. I understand that a patent claim will be invalid for lack of enablement if the patent specification does not teach one of ordinary skill in the art to make and use the full scope of the claimed invention without undue experimentation. I understand that a claim is enabled by the specification if the scope of the claim, as construed, bears a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

**6. Derivation**

37. I understand that a person is not entitled to a patent if that person did not invent the subject matter claimed. In other words, what you patent must be your own invention and you cannot patent another's invention. I also understand that the party asserting invalidity under this concept must show prior conception and that the conception was communicated to the patentee.

**7. Materiality**

38. I understand that 37 C.F.R. § 1.56, revised as of January 17, 1992, defines information "material to patentability" as follows: information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) it refutes, or is inconsistent with, a position the applicant takes in (i) opposing an argument of unpatentability relied on by the PTO, or (ii) asserting an argument of patentability.

39. As discussed below in the section entitled "The Undisclosed Patents And Other Information Are Highly Material," I have appropriately investigated whether certain information was "material to patentability" to the claims of the 278 Patent, not just those claims currently being asserted.

## III. TECHNOLOGY OVERVIEW

### A. Background Information

40. The 278 Patent is generally directed to a medication delivery device: a pen type device used for the administration of a medication such as insulin or human growth hormone from a cartridge.

41. For the past half century or so, patients suffering from diabetes have relied upon different types of medication delivery devices to administer their insulin. For example, in the United States, patients with diabetes have used a syringe and vial combination as a primary insulin delivery method.[6] In doing so, a patient obtains a vial of insulin and uses a syringe to withdraw or extract a dose from the vial. The patient then self-injects the dose.

42. Syringe use presents a few complications. For example, some patients are troubled by the discomfort and inconvenience that a needle and syringe injection might cause. Also, some patients do not want to carry around both a syringe and separate vial(s).[7] As a result, patients would oftentimes avoid taking their insulin. In addition, there is also a perceived stigma associated with using a syringe in public.

43. To solve these and other concerns, providers of insulin and manufacturers of medication delivery devices and their related items have developed alternative medication delivery

---

[6] In contrast, I understand that patients in Europe and other parts of the world have been using pen type devices for their insulin injections for almost twenty years.

[7] Certain patients suffering from diabetes often carry two or more such vials: one vial containing short acting insulin (providing a bolus injection) and a second vial containing long acting insulin (providing a basal injection).

devices.[8] Such alternative medication delivery devices include (1) infusion pumps, (2) injector delivery devices, and (3) insulin pens (disposable and non-disposable).

**1. Infusion Pumps**

44. Compared to the syringe and vial combination, infusion pumps are somewhat complicated devices. Such devices include a reservoir of insulin, a battery-operated pump, and some type of programmable electronics that controls the administration of insulin. Generally, these devices use a pump that is connected to a small diameter infusion set. This infusion set is attached to a needle that has been affixed to the body (*e.g.,* the abdomen) with the needle inserted into a person's subcutaneous tissue. These infusion pumps are typically quite discreet because they may be worn under clothing and are generally regarded as being accurate and reasonably convenient.

**2. Needleless Injector Delivery Devices**

45. Needleless injectors (which may be pen-shaped) are medication delivery devices that do not use a needle but rather use pressure to administer a dose of medicine. This dose of medicine may be injected through a user's skin. Alternatively, this dose may be dispensed through a user's nose. Injector delivery devices are preferred by some patients, such as those patients who have a fear of needles.

46. An example of such a prior art pen type injector medication delivery device is illustrated in U.S. Patent No. 5,331,954 ("Rex 954") (Exhibit C1).

---

[8] Providers of insulin and entities actively involved in the field of diabetes care at the time (*circa*, 1998) included at least Becton Dickinson and Company, Disetronic AG (ndba Ypsomed Holding AG), Eli Lilly and Co., Hypoguard (UK) Limited, Novo Nordisk A/S, Hoechst Aktiengesellschaft and Hoechst Pharma Deutschland (ndba collectively as sanofi-aventis), Medico Development Investment Co., Wilhelm Haselmeier GmbH & Co., and Owen Mumford Limited. These providers and their related entities are frequently identified on the patents, references, pen type delivery devices, and related items such as pen type needle assemblies that I have reviewed and operated.

### 3. Pen Delivery Devices

47. Pen delivery devices (so named because they often resemble an enlarged fountain pen) are generally comprised of three primary elements: (i) a cartridge section that includes a cartridge often contained within a housing or retainer; (ii) a needle assembly connected to one end of the cartridge section; and (iii) a dosing section connected to the other end of the cartridge section.

48. A cartridge (often referred to in the literature as an ampoule) typically includes a reservoir that is filled with a medication (*e.g.*, insulin), a movable rubber type bung or stopper located at one end of the cartridge reservoir, and a top having a pierceable rubber seal located at the other, often necked-down, end. A crimped annular metal band is typically used to hold the rubber seal in place. While the cartridge housing may be typically made of plastic, cartridge reservoirs have historically been made of glass.

49. An example of one prior art cartridge for use in a pen type medication delivery device is illustrated in U.S. Patent No. 5,549,574 ("Townsend 574") (Exhibit C2).

50. The needle assembly is typically a replaceable double-ended needle assembly. Before an injection, a replaceable double-ended needle assembly is attached to one end of the cartridge assembly, a dose is set, and then a dose is administered. Such removable needle assemblies may be threaded onto, or pushed (*i.e.*, snapped) onto the pierceable seal end of the cartridge assembly.

51. The dosing section is typically the portion of the pen device that is used to set a dose. During an injection, a plunger or pusher contained within the dosing section presses against the bung or stopper of the cartridge. This force causes the medication contained within the cartridge to be injected through the attached needle assembly.

52. After an injection, as generally recommended by pen device and/or needle assembly manufacturers and suppliers, the needle assembly is removed and discarded.

53. Different types of pen delivery devices, including reusable and disposable varieties, have evolved over the years.

a. Reusable Pen Type Medication Delivery Devices

54. Typical reusable pen delivery devices feature essentially two main reusable components: a cartridge housing and a dosing section. After a cartridge is inserted into the cartridge housing, the housing is attached to the dosing section. Before an injection, a replaceable double-ended needle assembly is attached to the cartridge housing. This needle assembly may be threaded onto or pushed onto (*i.e.,* snapped onto) a pierceable seal end of the cartridge. After an injection, the needle assembly is removed and discarded. After the insulin in the cartridge has been exhausted, the user detaches the cartridge housing from the dosing section. The user can then remove the empty cartridge from the cartridge retainer and replace the empty cartridge with a new (filled) cartridge.

55. Most reusable insulin pen delivery devices are single cartridge devices: they accept a single cartridge at a time. Such single cartridge pen type devices can be used with cartridges having different types of insulin preparations. For example, such cartridges could contain a quick or short-acting insulin (typically injected before meal time) or a long-acting insulin (typically taken to cover a basal need of the patient). However, certain pen type devices have also been developed that contain both types of cartridges. Such dual cartridge pen type devices enable a user to administer a single dose prepared from two types of insulin: for example, a dose having both quick-acting and long-acting insulin. Such dual cartridge pen syringes would have two separate dose setting sections: a first dose setting section for setting the quick-acting dose and a second dose setting section for setting the prolonged action insulin preparation. In this manner, a user could use the dual cartridge device to inject a single mixed dose.

56. An exemplary prior art single cartridge reusable insulin pen delivery device is disclosed in U.S. Patent No. 5,921,966 ("Bendek 966") (Exhibit C3). Exemplary prior art dual cartridge reusable insulin pen delivery devices are disclosed in U.S. Patent No. 5,314,412 ("Rex 412") (Exhibit C4) and in U.S. Patent No. 5,584,815 ("Pawelka 815") (Exhibit C5).

57. The 278 Patent is generally directed to such pen-type delivery devices and is not specific as to whether it is a reusable or disposable. The 278 Patent is directed to a specific mechanism "for injection of set doses of medicine from a cartridge," where a dose is set by "screwing a nut up along a threaded piston rod" through the operation of direct gearing (gearbox) that connects an injection button with a dose dial drum to the nut. Injection occurs when the button is pushed by the user and the gear box transfers this axial movement to the nut. Abstract. Further, a "gear wheel transmission is established between the nut and the injection button." Abstract. No alternative mechanism is disclosed in the 278 Patent to connect the nut to the injection button.

b. Disposable Pen Type Medication Delivery Devices

58. Disposable pen delivery devices are supplied as self-contained devices. These self-contained devices do not have removable pre-filled cartridges. Rather, the pre-filled cartridges may not be removed and replaced from these devices without destroying the device itself. Consequently, the disposable pen delivery devices (as the name implies) are simply thrown away after the medication in the pen has been expended. One perceived advantage of such disposable devices is that the pen device user does not have to disassemble the device to remove an empty cartridge. However, with such disposable pen devices, the user is still called upon to repeatedly attach and then remove (after an injection) a needle assembly.

59. An example of such a prior art disposable insulin pen delivery device is disclosed in U.S. Patent No. 4,973,318 ("Holm 318") (Exhibit C6).

60. One of ordinary skill in the art during the relevant time period (circa 2000) would have been aware of at least these various types of medication delivery devices and their associated needle assembly types and would have relied upon these items for their teachings.

## IV. OPINIONS REGARDING THE 278 PATENT

### A. The 278 Patent

61. The 278 Patent was filed on September 22, 2003, issued on July 10, 2007 and claims priority to two U.S. provisional patent applications Nos. 60/275,790 filed March 14, 2001 and 60/214,470 filed June 27, 2000. The 278 Patent also claims priority to two Danish applications, one filed on June 16, 2000 and the other on March 7, 2001. Therefore, assuming that the 278 Patent is entitled to the earliest Danish filing date, a relevant prior art date is June 16, 2000. The 278 Patent is attached as Exhibit D1.

### B. The Particular Problem Allegedly Faced by the Inventors of the 278 Patent

62. The 278 Patent is directed to a medication delivery device that has a very specific design according to the inventor that was necessitated by the industry change from 1.5 ml cartridges to 3 ml medication cartridges. Exhibit D1, 278 Patent, Col. 1, Lines 36-54. This change caused several problems as indicated by the inventor and reproduced below.

> As it has not been appropriate to make the syringe longer the ampoule is instead given a larger diameter, i.e. the area of the piston facing the medicament in the ampoule has been doubled and consequently the force which has to be exerted on the piston to provide the same pressure as previously inside the ampoule has been doubled. Further the distance the piston has to be moved to inject one unit of the medicament has been halved.
>
> This development is not quite favourable, as especially users having reduced finger strength have their difficulties in pressing the injection button, a problem that is further increased when still thinner needles are used to reduce the pain by injection. Also with quite small movements of the button it is difficult to feel whether the button is moved at all and by injection of one unit from a 3 ml ampoule the piston and consequently the injection button has to be moved only about 0.1 mm.

Exhibit D1, 278 Patent, Col. 1, Lines 36-54. These problems created

> a wish for a gearing between the injection button and the piston has occurred so that the button has a larger stroke than has the piston. By such a gearing the movement of the injection button is made larger and the force, which has to be exerted on the injection button, is correspondingly reduced.

Exhibit D1, 278 Patent, Col. 1, Lines 55-60. Novo's inventor indicates that those skilled in the art

recognized the problems and more importantly recognized the solution, i.e. "gearing."

63. Novo's inventor described three prior art patents in the background section of the 278 Patent as all having the requisite "gearing" to solve the problems caused by the larger 3 ml cartridges. Novo's inventor dismissed and criticized the first two prior art "gearing" solutions as inefficient because in

> this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces.

Exhibit D1, 278 Patent, Col. 2, Lines 4-7. The inventor went on to conclude,

> [t]herefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

Exhibit D1, 278 Patent, Col. 2, Lines 7-8. Such a "traditional gearing using mutual engaging gear wheels and racks" solution was also known to the prior art and was admitted to as such by Novo's inventor when he cited to the third prior art patent (WO 99/38554) in the background section. Exhibit D1, 278 Patent, Col. 2, Lines 9-34. Novo's inventor admitted that this prior art device had "two integrated gear wheels engages a rack fixed in the housing and a rack inside a plunger, respectively." Again, Novo's inventor criticized this design indicating that,

> [a] disadvantage by this construction is that the teeth of the racks and gearwheels alternating have to be brought in and out of engagement with each other with the inherit danger of clashing.

Exhibit D1, 278 Patent, Col. 2, Lines 35-38. In summary, Novo's inventor admitted that the solution to the problems caused by the larger 3 ml cartridges ("further increased when . . . thinner needles are used") was to use gearing and specifically "***traditional gearing using mutual engaging gear wheels and racks,"*** but ***only*** a specific type of "traditional gearing" is disclosed where gear wheels and racks are ***not "brought in and out of engagement with each other."*** This acknowledged restriction by Novo's inventor significantly limits the dose setting/injection mechanism that is claimed by 278 Patent.

64. After limiting the solution to the use of a specific type of gear wheel and rack combination, the inventor next stated that the objective of his 278 Patent was to

> provide an injection device, which combines the advantages of the devices according to the prior art ***without*** adopting their disadvantages and to provide a device wherein is established a ***direct gearing, i.e. a gearing by which more transformations of rotational movement to linear movement and linear movement to rotational movement are avoided***, between the injection button and the piston rod.

Exhibit D1, 278 Patent, Col. 2, Lines 42-49. In other words, the claimed device must necessarily include a "direct gearing" component, which is a specific type of "traditional gearing" as stated by Novo's inventor. This specific "direct gearing" must be located between an injection button and a piston rod. Further, this "direct gearing" must function to eliminate conversions of (1) rotational movement to linear movement and (2) linear movement to rotational movement. The only mechanical component illustrated or described in the 278 Patent to accomplish the "direct gearing" is the "gear box" comprised of "at least one gear wheel engaging the first and second rack." *See*, e.g, Exhibit D1, 278 Patent, Col. 3, Lines 1-18. In fact, the inventor stated that his device is

> characterised in that a ***gearbox*** is provided which provides a gearing between the ***axial movements*** of the injection button and the nut relative to the housing which gearing has a gearing ratio corresponding to the ratio of said second and first pitch.

Exhibit D1, 278 Patent, Col. 2, Lines 61-65. The direct gearing structure, which Novo's inventor interchangeably refers to as a "gearbox," allows for the axial (linear) movement of the injection button to be transferred to axial movement of the nut and piston rod without rotational movement. The Abstract of the 278 Patent confirms the location of this mechanical direct gearing component; "[a] gear wheel gear transmission is establish between the nut and the injection button."

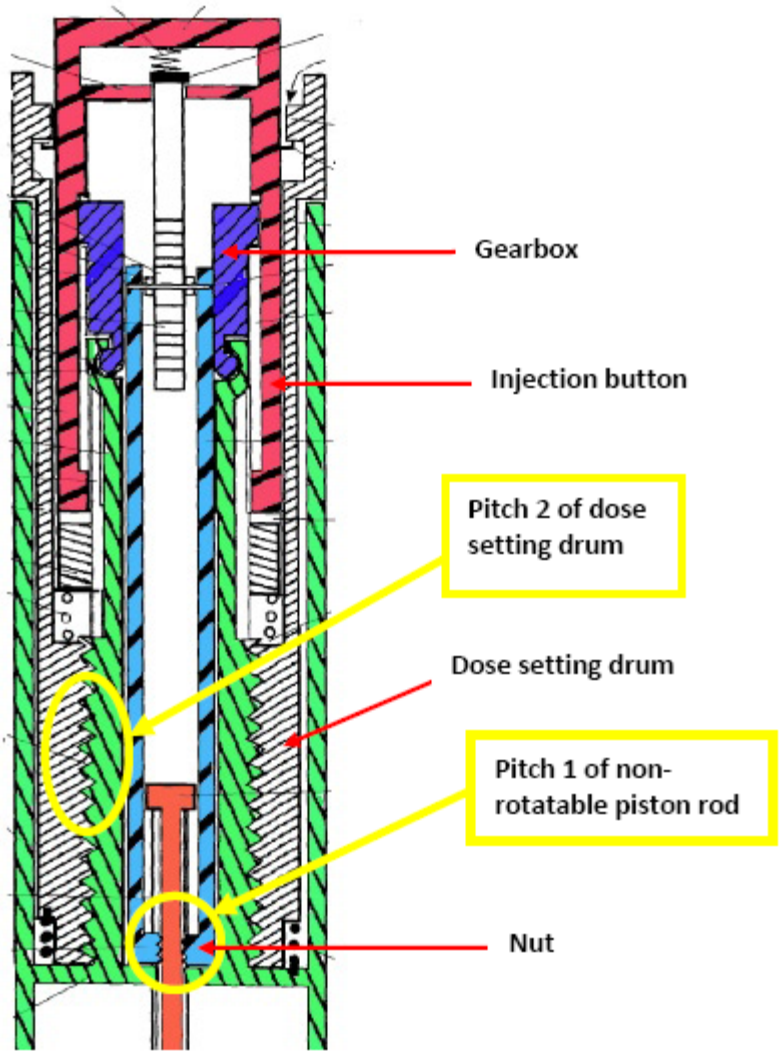
65. The 278 Patent includes only two embodiments of the claimed "drug delivery device," both of which include direct gearing. The 278 Patent does not discuss, disclose or suggest any embodiment of the claimed invention that does not include direct gearing. The figures of the 278 Patent are introduced by a statement that "***the invention*** is described in further details with references to the drawing." Exhibit D1, 278 Patent, Col. 3, Lines 29-30. Figure 1 is described as showing

"an injection device according to ***the invention***" while Figure 2 is described as "showing a sectional view of the gearbox" from Figure 1. Exhibit D1, 278 Patent, Col. 3, Lines 31-34.

66. The necessity of direct gearing to the device claimed in the 278 Patent is further confirmed by examining the operation of the device during dose setting as described in the patent specification. The Novo inventor states that the above-stated objective of his injection is achieved with,

> an injection device comprising a housing wherein ***a piston rod threaded with a first pitch is non rotatable*** but longitudinally displaceable guided, ***a nut engaging the thread of the piston rod*** which nut can be screwed along the threaded piston rod away from a defined position in the housing to set a dose and can be pressed back to said defined position carrying the piston rod with it when the set dose is injected, ***a dose setting drum*** which can be screwed outward in the housing along a thread ***with a second pitch*** to lift an injection button with it up from the proximal end of the housing, which injection device is according to the invention ***characterised in that a gearbox is provided which provides a gearing between the axial movements of the injection button and the nut relative to the housing which gearing has a gearing ratio corresponding to the ratio of said second and first pitch.***

Exhibit D1, 278 Patent, Col. 2, Lines 50-65. During dose setting, the dose setting drum is rotated about threads having a "second pitch" (the distance between threads) that is greater than the "first pitch" of the threads on the non-rotatable piston rod. Most importantly, the direct gearing structure is the mechanism that must compensate for "the ratio of said second pitch and first pitch." Only a single value for this thread pitch ratio is disclosed in the 278 Patent, that being a ratio of 2:1. Col. 5, Lines 65-67 7 Col. 6, Lines 1-5. In other words, the distance between the threads on the dose setting drum is twice that of the distance between the threads on the non-rotatable piston rod. This can be seen in Fig. 1 of the 278 Patent.




When setting a dose, the dose setting drum is rotated thus causing the "nut [to] be screwed along the threaded piston rod away from a defined position in the housing." Because the pitch of the threads between the dose setting drum and piston rod/nut are different by a factor of 2, for example, there cannot be a direct connection between these two parts. There must be a mechanism in between the dose setting drum and piston rod/nut that ***compensates*** for this difference in thread pitch; otherwise the device would jam about the smaller pitched threads of the rod/nut, thus preventing a user from either setting a dose or injecting a dose. That mechanism is the "direct gearing."

67. The specification describes the compensation provided by the direct gearing of the device at Col. 5, Lines 23-34, where Novo's inventor states that,

> the axial movement of the nut 13 relative to the housing 1 will be transmitted to the gear wheel assembly through the connection bars 12 and this movement will ***through the gearbox*** induce an outward movement of the rack 15. This induced outward movement have to be the same as the outward movement induced by outward movement of the injection button. ***This is obtained by dimensioning the gear wheels of the gearbox 9 so that the gear ratio for the movements of the connection bars 12 and the rack 15 relative to the housing corresponds to the ratio of the pitches for the thread on the piston rod and for the thread 6 for the longitudinal movement of the dose setting drum 17***.

As mentioned, no other mechanism is mentioned in the 278 Patent to provide the compensation for the pitch ratio of the threads. Accordingly, in order to set a dose with the claimed device, direct gearing must be used.

68. Direct gearing is ***also*** necessary in order to ***inject*** a set dose. To achieve the objectives set by Novo's inventor, that being to avoid transforming rotational movement to linear movement and vice versa, linear movement of injection button must cause only linear movement of the nut and the piston rod to which it is attached. The 278 Patent describes this at Col. 5, Lines 35-43.

> To inject a set dose the injection button is pressed by pressing on the bottom 19. In the initial phase of the pressing the spring 31 is compressed where after the pressing force is directly transmitted to the head 29 of the rack 15 and this way to the rack 15 itself. ***Through the gear box 9*** the force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2.

The Novo inventor further states that,

> the forces necessary to move the piston by injection is transmitted to said piston ***through a conventional gear with constantly engaging gears and racks.***

Exhibit D1, 278 Patent, Col. 3, Lines 21-23. Accordingly, to inject a dose with the claimed device, a direct gearing component is absolutely necessary to accomplish the objectives stated by the Novo inventor.

69. Just as the specification limits the claims to an injection device that includes "direct

gearing," the specification similarly makes clear that the invention is limited to an injection device including a piston rod that cannot rotate in response to an injection force.

> A threaded ***piston rod 4 has a not round cross section*** by which it fits through a central opening in the wall 2 so that the piston rod 4 can be displaced longitudinally through the central opening in the wall 2 ***but not rotated*** relative to this wall.

Exhibit D1, 278 Patent, Col. 3, Lines 21-23. This non-circular, non-rotatable piston rod is illustrated as item 104 in Fig. 5 of the patent, which shows one of the two flat sides of the rod that is keyed to another part of the device that allows ***only*** linear movement of the rod and ***not*** rotation. No other embodiments of the piston rod are described, illustrated, discussed, or mentioned in the 278 Patent.

70. The requirement that the piston rod ***not*** rotate is completely consistent with the required direct gearing. It is also in accordance with the stated objective of the invention, *i.e.*, to avoid transformations of rotational movement to linear movement and vice versa. In order to accomplish this objective and to obtain the benefits of the gearbox, the piston rod must not rotate – it must be driven linearly by the direct gearing component. The specification of the '278 patent states that this objective is accomplished

> by an injection device comprising a housing wherein a ***piston rod*** threaded with a first pitch ***is non rotatable*** but longitudinally displaceable guided

Exhibit D1, 278 Patent, Col. 2, Lines 50-52. Indeed, if the piston rod is allowed to rotate, an accurate dose cannot be set, let alone administered. More specifically, if the rod were allowed to rotate, the nut would not reliably thread up the rod during dose setting because the rod would ***also*** tend to turn when the nut is turned.[9]

71. Accordingly, in order to fulfill the objectives stated by Novo's inventor, the claimed device must have a non-circular piston rod that does not rotate during dose setting or injection of a dose.

---

[9] Incorrect or unreliable dose setting and dose administration in an insulin based medication delivery device, such as the device illustrated in and claimed in the 278 patent, can lead to death.

**C. The 278 Patent Claims**

72. The 278 Patent issued with twenty-eight claims. I understand that Novo asserts only claims 1 and 7-26. Claims 1, 8, 12, 16, 22 and 25 are the only asserted independent claims.

Each of the asserted claims requires both structural and functional claim limitations. The functional limitations are directed to the movement of the structural components during (1) "dose setting" and (2) "injecting" ("injection" or "dose administration") In general, each of the asserted claims require that during "dose setting," two structural components rotate together to set a dose, and upon "injection," these same two components are uncoupled such that one component rotates and the other moves only in an axial direction. The claimed functionality of each of these steps is directly dependent upon the structural components of the claimed device. In order for the device to function as claimed, each of the asserted claims must include at least two additional structural elements that in some claims are not specifically stated. Those missing structural elements are the "piston rod" (Claims 8 and 12) and the "gearbox" or "direct gearing" (all claims). The direct gearing comprises "at least one gear wheel engaging the first and second rack." Col. 3, Lines 10-11. When the dose is injected, "the force necessary to make the injection is transmitted to the piston rod 4 through the gearbox 9." Col. 5, Lines 52-54. Further, as noted above, the specification states that "a traditional gearing using mutual engaging gear wheels and racks is preferred." Col. 21, Lines 7-8.

**D. Claim Construction**

73. I understand that the proper construction or understanding of the asserted claims is a matter of law for the Court to decide.

74. I have reviewed the claims and believe that certain terms, as set forth below, must be construed to have a meaning to a person of ordinary skill in the art that differs from the ordinary meaning. I also understand that any language not so identified will be construed according to its

ordinary meaning. Where applicable, I have identified claim terms for which the inventors chose to give a meaning different from the term's ordinary meaning. I also understand the same claim term in one claim must be construed the same when it appears in another claim.

75. I understand that the language of a claim generally carries the ordinary meaning of the words in their normal usage in the field of the invention at the time of the invention. I also understand that the construction of the claims of the patent-in-suit does not change whether that construction is being applied for purposes of infringement or invalidity.

76. I understand that discovery is ongoing and I reserve the right to supplement and amend this declaration if additional pertinent information comes to my attention. I also reserve the right to supplement and amend this declaration based upon any agreements by the parties or claim construction rulings by the Court.

77. Claim 1 is fairly representative of each of the independent claims as it recites four structural elements: 1) "a piston rod" (4) that drives a stopper in a cartridge of medication to expel a dose; 2) "a dose dial sleeve (17) threadedly engaged with a portion of the device" that is rotatable to a position indicating the amount of medication to be delivered; 3) "a drive sleeve (20) for driving the piston rod" in response to pressure exerted by the user; and 4) "a clutch (21)" to couple and de-couple the dose dial sleeve and the drive sleeve.[10] Claim 1 also has the two functional limitations, (1) "dose setting" and (2) "injecting." These two functional limitations have very specific meanings, as defined below. They require specific movements of the above-mentioned structural claim elements and, more importantly, must include the specific structural elements to allow those movements.

78. The complete claim 1 reads as follows (with structural and functional elements emphasized and highlighted in ***teal***):

---

[10] I note that the Novo inventors never use the terms "dose dial sleeve," "drive sleeve," and "clutch" in the written description of the 278 patent.

**1.** A drug delivery device comprising:

a ***piston rod*** having at least one threaded portion (4);

a ***dose dial sleeve*** (17) threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale;

a ***drive sleeve*** (20) for driving the piston rod; and

a ***clutch*** (21), which is comprised of one or more components (33, 32), that releasably couples the dose dial sleeve (17) and the drive sleeve (20); and wherein:

(i) during the ***dose setting*** operation the dose dial sleeve (17) and the drive sleeve (20) are coupled by the clutch so that they rotate together; and
(ii) during ***injecting*** of medication from the device, the dose dial sleeve (17) is decoupled from the drive sleeve (20) and so that it rotates back to an original pre-dose setting position upon completion of the injection but the drive sleeve (20) does not rotate during injecting of medication but instead moves in a longitudinal direction toward an injecting end of the device.

The claim term "dose setting" must be construed to require specific movements of a combination of parts that are interrelated. The 278 Patent defines "dose setting" in only one manner, that being the rotation of a "nut" along the threads of the piston rod. The distance the nut is screwed up along the threads equals the amount of medication to be delivered. This is evident from the patent specification:

> a dose is set by screwing a nut up along a threaded piston rod. Abstract.
>
> This can be obtained by an injection device comprising a housing wherein a piston rod threaded with a first pitch is non rotatable but longitudinally displaceable guided, a nut engaging the thread of the piston rod which nut can be screwed along the threaded piston rod away from a defined position in the housing to set a dose. Col. 3, Lines 50-55.
>
> a nut engaging the thread of the piston rod which nut can be screwed along the threaded piston rod away from a defined position in the housing to set a dose. Col. 3, Lines 52-54.
>
> To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6. Col. 4, Lines 51-52.

> The rotation of the dose setting button 18 and the cup shaped element is further transmitted to the gearbox 9 . . . . The rotation of the gearbox 25 is through the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose it set. Col. 5, Lines 8-12.
>
> Also the axial movement of the nut 13 relative to the housing 1 will be transmitted to the gear wheel assembly through the connection bars 12 and this movement will through the gearbox induce an outward movement of the rack 15. This induced outward movement [has] to be the same as the outward movement induced by outward movement of the injection button. This is obtained by dimensioning the gear wheels of the gearbox 9 so that the gear ratio for the movements of the connection bars 12 and the rack 15 relative to the housing corresponds to the ratio of the pitches for the thread on the piston rod and for the thread 6 for the longitudinal movement of the dose setting drum 17. Col. 5, Lines 23-34.

Moreover, "dose setting" is further defined in that the distance the "nut" travels along the threads of the piston rod must be less than the distance traveled by the "dose dial sleeve" and "drive sleeve" (i.e. the "injection button").

> a dose setting drum . . . and an injection button, which is elevated over the end of the syringe, are moved axially a distance which is larger than the axial movement of the nut. Abstract.

This is accomplished because the piston rod has a thread pitch smaller than the thread pitch of the dose setting sleeve.

> a piston rod threaded with a first pitch. Col. 2, Line 51.
>
> a dose setting drum which can be screwed outward in the housing along a thread with a second pitch to lift an injection button with it up from the proximal end of the housing, which injection device is according to the invention characterised in that a gearbox is provided which provides a gearing between the axial movements of the injection button and the nut relative to the housing which gearing has a gearing ratio corresponding to the ratio of said second and first pitch. Col. 3, Lines 50-55.

As indicated, the difference in thread pitch between the piston rod and the dose setting sleeve requires that a "direct gearing" component is needed to compensate for the ratio of the different thread pitches. If a "gearbox" were not provided, it would be impossible to set a dose because rotation of the larger pitched dose dialing sleeve would cause binding of the smaller pitched nut as it tried to screw up the piston rod. This was confirmed by Novo's witness, Mr. Clemens,

> **Q. If the dose setting drum is connected to the tubular part and the tubular part is connected to the nut without a gearbox, and there is different threads, different pitched threads, will that device function?**
> . . .
> A. Well, hopefully I am imagining what you are imagining, but I think I understand what you are asking. You would have obviously two threads working against each other in that instance.
> **Q. And that would jam?**
> A. That would jam.
> **Q. That would jam whether you are setting a dose or injecting a dose, correct?**
>
> Page 131
> A. Right.

Exhibit D5 Clemens deposition, page 130.

79. The construction of the claim term "injecting" also requires that claim 1 necessarily include "direct gearing." As mentioned, during dose setting the direct gearing component allows the nut to be screwed up the piston rod a distance equal to the amount of the dose of medicine to be injected. However, the drive sleeve (injection button) moved twice that distance because the pitch of the threads of the dose dial sleeve is twice that of the nut and piston rod. Upon injection, the drive sleeve is moved in an axial direction back to its starting point and pushes on the nut attached to the piston rod back to the nut's original starting point. The result is that the drive sleeve travels twice the distance of the nut. There must be some mechanical structure that compensates for this difference in distances otherwise the drive sleeve would never return to its starting position. That mechanical structure is the "gearbox" or "direct gearing." This is clearly set forth in the specification.

> a nut engaging the thread of the piston rod . . . be pressed back to said defined position carrying the piston rod with it when the set dose is injected, a dose setting drum which can be screwed outward in the housing along a thread with a second pitch to lift an injection button with it up from the proximal end of the housing, which injection device is according to the invention characterised in that a gearbox is provided which provides a gearing between the axial movements of the injection button and the nut relative to the housing which gearing has a gearing ratio corresponding to the ratio of said second and first pitch.

Col. 2, Lines 52-65.

> only the forces necessary to drive the dose setting drum are transformed by a thread with a high pitch whereas the forces necessary to move the piston by injection is transmitted to said piston through a conventional gear with constantly engaging gears and racks.

Col. 3, Lines 19-23.

> "To inject a set dose the injection button is pressed by pressing on the bottom 19. In the initial phase of the pressing the spring 31 is compressed where after the pressing force is directly transmitted to the head 29 of the rack 15 and this way to the rack 15 itself. Through the gear box 9 the force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2."

Col. 5, Lines 19-43.

The "drive sleeve" is required to have a specific function, that of "driving the piston rod" into the ampoule during the "injecting" step in order expel medication from the cartridge through a needle and into the patient. The only embodiment described or illustrated in the specification that allows the transfer of injection force from the "drive sleeve" to the piston rod is through the direct gearing mechanism, specifically a "gearbox." Indeed, the specification states that

> only a force sufficient to make the dose setting drum screw itself downward along the thread 6 is necessary ***as the force necessary to make the injection is transmitted to the piston rod 4 through the gearbox 9***.

Col. 5, Lines 50-54.

80. The prosecution histories of the 278 Patent support the above claim construction. During the prosecution of the parent application, which ultimately issued as U.S. Patent No. 6,663,602, the Examiner rejected the claims as anticipated by Novo's own prior art (U.S. Patent No. 5,626,566 to Peterson et al. – Exhibit C7). Novo argued the importance of the "nut" and "direct gearing" (as a "gear box") in the claimed device during dose setting as follows:

> The '566 patent does not disclose each and every limitation of the invention as defined by the pending claims. In particular, ***the claims require a nut that is axially displaceable***, with respect to the housing, from a first position to a second position. ***The nut moves relative to the housing, from a first position to a second position by being screwed along the thread of the piston rod during a dose setting operation.*** The linear displacement of the nut defines the size of the dose that will be administered by the device.

> . . .
>
> The presently pending claims require that the nut move axially with respect to the housing along the piston rod. ***This is accomplished by screwing the nut along the threads of the piston rod. The nut is driven by the gearbox in a linear direction*** toward the distal end of the housing, without rotation. Since the nut [is] screwed onto the piston rod, the nut is axially displaced when the gear box axially displaces the nut. ***Thus, the applicants' invention uses a gearbox to couple axial movement of the injection button to axial movement of the nut***, which is in turn coupled to the piston rod to produce axial movement of the piston rod. The nut acts to limit movement of the piston rod in a distal direction by abutting an abutment within the housing. The gearbox of the present invention drives the nut axially without necessarily rotating it to expel a dose from the injection device.

Novo's Response to 1st Office Action, Dec. 2, 2002 - Exhibit C8. Novo repeated the importance of the "nut" in defining the dose being set in response to a second rejection by the Patent Examiner.

> Claim 5 has been amended ***to point out more clearly that the nut is displaceable relative to the housing*** of the device and that the ***nut screws along a piston rod in a proximal direction from a first position to a second position.*** It is this ***displacement of that nut that defines the size of the dose*** of medicine to be injected by the device because the amount of displacement of the nut defines how far the piston rod may move in a distal direction relative to the housing of the device.

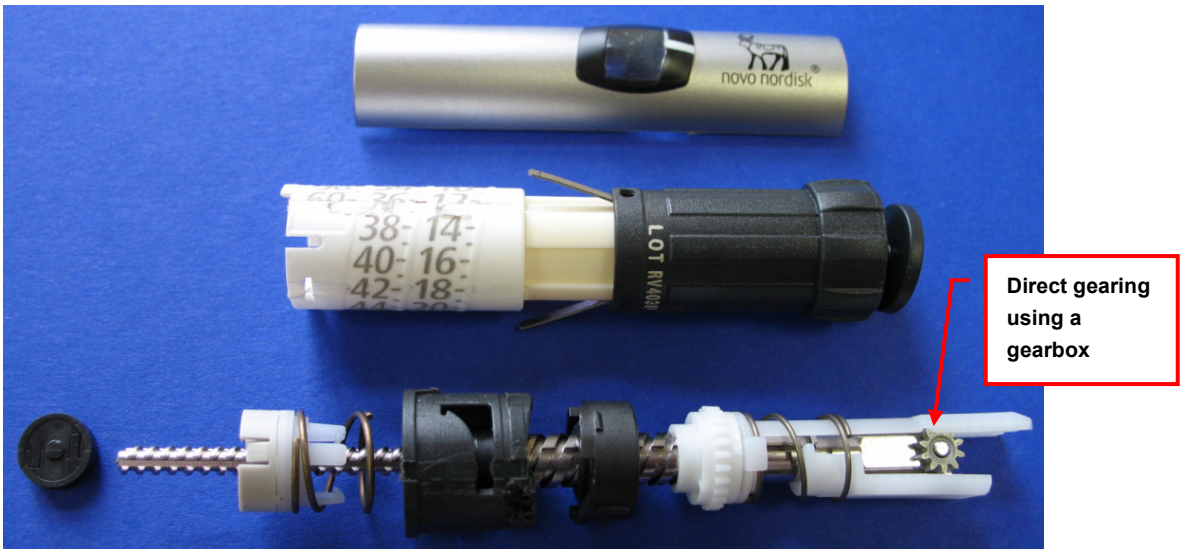
Novo's Response to 2nd Office Action, May 23, 2003 – Exhibit C9. As Novo told the Examiner, "***the applicants' invention*** uses a gearbox to couple axial movement of the injection button to axial movement of the nut," confirming the description in the 278 Patent specification that direct gearing is a necessary and integral structural feature of the claimed invention. In addition, throughout the 278 Patent specification and the file histories, Novo used the term "gearbox" as shorthand for "direct gearing." In non-asserted claims 2 and 4, the term "gearbox" is used. However, in these instances, Novo's inventor was limiting the "gearbox" to a specific configuration of "direct gearing" to transfer and multiply specific forces during injection.

81. The prosecution history also contains a letter to the Examiner dated April 9, 2007 from Novo's legal representative, Mr. Began, where Mr. Began acknowledged that the claimed invention is the commercially available NovoPen 4 pen injection device. Exhibit C10.

> At the in person interview, Applicants' attorney discussed the pending claims with the Examiner and distinguished the Burroughs reference and other prior art in general by

showing the Examiner how the Applicants' invention works. The NovoPen 4 device was shown the Examiner and it was contrasted with the prior art.

The NovoPen 4 device, as shown in the photograph below, clearly has "direct gearing." Additional details of the NovoPen 4 are shown and described in Exhibit C11.




82. Accordingly, the claim 1 terms "dose setting" and "injecting," as well as "driving the piston rod," each must be construed to require the use of "direct gearing," *i.e.*, a "gearbox." This "direct gearing" is defined by the 278 Patent as being located between the injection button and the piston rod and must function to eliminate the conversions of (1) rotational movement to linear movement and (2) linear movement to rotational movement. Finally, "direct gearing" must comprise "at least one gear wheel engaging [a] first and second rack" as described at Col. 3, Lines 1-18.

83. The "piston rod" of claim 1 must be non-rotatable and have a cross-section that is not round. The 278 Patent, Col. 3, lines 46-47. If the piston rod were allowed to rotate on dose setting, the nut could not be accurately screwed up the threads on the rod, resulting in an incorrectly set dose. Additionally, if the rod were allowed to rotate upon injection, it would likely rotate within the nut and the dosing error would be compounded.

84. The claim element "clutch" (or "coupling") also has a specific meaning in Claim 1. Indeed, the claim itself requires that the

> clutch (21) be comprised of one or more components (33, 32), that releasably couples the dose dial sleeve (17) and the drive sleeve (20)

The patent specification also equates the terms "clutch" to "coupling" by using the same element number (21).

> Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17

Col. 4, lines 52-54. The 278 Patent specification, however, discloses only one type of clutch/coupling. That being where one component is integral to the "dose dial sleeve" (or "tubular element") and the complementary component is integral to the "drive sleeve." *See, e.g.,* The 278 Patent, Fig. 1, items 32 & 33; Fig. 5, items 133 & 132; Col. 4, Line 68 - Col. 5, Lines 1-3. These complementary components take the form of opposing "A" shaped teeth, which are clearly shown in Fig. 5 as items 132 and 133. These two components are also described in the specification as

> the coupling 21, which may comprise A-shaped protrusions 32 on the cup shaped element engaging A-shaped recesses in an inner ring 33 in the dose setting button

Col. 4, Line 68; Col. 5, Lines 1-3.

> During the initial phase of the movement of the injection button the A-shaped protrusions 32 on the cup shaped element will be drawn out of their engagement with the A-shaped recesses in the ring 33. The dose-setting drum 17 can now rotate relative to the injection button and will do so when the A-shaped protrusions 32 press against a shoulder 34 at the bottom of the dose setting button 18.

Col. 5, Lines 44-50. No other structure for the coupling/clutch is disclosed. Accordingly, the proper construction of the claim term "clutch" ("coupled" or "coupling") is a configuration comprised of two complementary components, where one is integral to the "dose dial sleeve" and the other integral to the "drive sleeve." I note that Novo's witness, Mr. Clemens, has confirmed that the claimed "clutch" must comprise at least two components.

> 16 **Q. And my question is, does a coupling**
> 17 **require one or more components?**
> . . .
> 20 A. Yes, a coupling requires at least two,
> 21 I would think, yes.

Exhibit D5, Clemens deposition, page 81.

85. The other five independent claims (8, 12, 16, 22 & 25) are reproduced below with the same structural and functional elements as Claim 1 emphasized and highlighted in ***teal.***

**8.** A drug delivery device and drive mechanism comprising:

a housing (1);

a ***dose dial sleeve*** (17) threadedly engaged with a threaded portion of the device, the threaded portion being located between a first end of the device and a second end of the device,

a ***drive sleeve*** (20), and

a ***clutch*** releasably coupling the dose dial sleeve and the drive sleeve (20),

wherein, when the dose dial sleeve (17) and the drive sleeve (20) are coupled during ***dose setting***, both are allowed to rotate with respect to the housing (1),
and when the dose dial sleeve (17) and the drive sleeve (20) are de-coupled during ***dose administration***, rotation of the dose dial sleeve (17) with respect to the housing (1) is allowed, while rotation of the drive sleeve (20) with respect to the housing (1) is not allowed, whereby axial movement of the drive sleeve is allowed so that a force is transferred in the longitudinal direction to the first end of the drug delivery device.

**12.** A drug delivery device and drive mechanism comprising:

a housing;

a ***dose dial sleeve*** threadedly engaged with a portion of the device, the portion being located in between a needle end of the device on which a needle is mountable and an opposite end of the device,

a ***drive sleeve***,

and wherein the dose dial sleeve and the drive sleeve are releasably ***coupled*** together so that:

during ***dosing setting***, the dose dial sleeve and the drive sleeve are coupled and both the dose dial sleeve and the drive sleeve rotate together with respect to the housing and

during ***dose administration*** the dose dial sleeve and the drive sleeve are de-coupled and the dose dial sleeve rotates with respect to the housing and the drive sleeve moves axially toward the needle end without rotating with respect to the housing.

**16.** A medication delivery device for expelling settable doses of medication, the device comprising:

an injection end,

a housing,

a ***dose setting drum*** comprising a scale indicating various dose sizes, and a ***tubular element*** that is reversibly rotationally ***coupled*** to the dose setting drum so that during ***dose setting*** the tubular element and the drum rotate together but during ***dose administration*** the tubular element is rotationally decoupled from the drum so that the drum rotates back to a zero position while the tubular element moves longitudinally toward the injection end,

the device further comprising a ***rod*** that comprises a first threaded portion that extends thru a portion of the housing, the rod coupled to the tubular element so that when the tubular element moves toward the injection end of the device, the rod also moves toward the injection end but wherein the rod travels a different distance than the tubular element, and wherein the tubular element and drum move away from the injection end during dose setting and move axially toward the injection end when a force is applied to either one or applied to both during dose administration.

**22.** A drug delivery device comprising:

a ***piston rod*** (4);

a ***dose dial sleeve*** (17) threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale;

a ***drive sleeve*** (20) for driving the piston rod; and

a clutch that releasably couples the dose dial sleeve (17) and the drive sleeve (20); and wherein: (i) during the ***dose setting*** operation the dose dial sleeve (17) and the drive sleeve (20) are coupled by the ***clutch*** so that they rotate together; and (ii) during ***injecting*** of medication from the device, the dose dial sleeve (17) is decoupled from the drive sleeve (20) and so that it rotates back to art original pre-dose setting position upon completion of the injection but the drive sleeve (20) does not rotate during injecting of medication but instead moves in a longitudinal direction toward an injecting end of the device.

**25.** A drug delivery device comprising:

a ***piston rod***;

a ***dose dial*** threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale;

a ***drive sleeve*** for transmitting a force that is received at one end of the device to drive the piston rod; and

wherein the dose dial and the drive sleeve are releasably ***coupled*** so that when the device is in a ***dose setting*** mode, the dose dial and drive sleeve rotate together and allow a predetermined dose to be set, and during the ***injection*** of the predetermined dose the dose dial and the drive sleeve are decoupled and the dose dial rotates with respect to the drive sleeve and rotates to a zero position upon completion of the injection and the drive sleeve moves axially toward an injecting end of the device and

> wherein the drive sleeve moves a distance that is greater than a distance that is moved by the piston rod during the injecting of the predetermined dose.

86. As is evident from a review of the above independent claims (8, 12, 16, 22, & 25), each require the same three ***structural*** components as Claim 1 – a "dose dial sleeve," a "drive sleeve," and a "clutch" (coupling). Likewise, each contains the same two ***functional*** elements as Claim 1, "dose setting" and "injecting" ("injection" or "dose administration"). All but Claims 8 and 12 also contain the same "piston rod" as Claim 1, however, the devices claimed in Claims 8 and 12 must contain the same piston rod as claimed in the other independent claims otherwise the device would not operate. Further, the piston rod in Claims 8 and 12 must also be non-rotatable and not have a circular cross-section.

87. I understand that identical claim terms should be construed consistently. That is, where identical claim terms are used in multiple claims in the same patent, those terms should be given identical meaning. This is true unless the inventor clearly indicate that an identical claim term in one claim has a different interpretation in another claim.

88. Therefore the construction of the claim terms as discussed for Claim 1 are the same as for the other independent claims being asserted by Novo.

**E. SoloStar® Does Not Infringe Any Asserted Claims**

89. I have examined the SoloStar® injection device manufactured and sold by sanofi-aventis. I also reviewed a video showing an animation of the operation of the SoloStar® device (STR0002212).

90. The SoloStar® device does not infringe any of the asserted independent claims of the 278 Patent. Because the independent claims are not infringed, any claims that depend from them are likewise not infringed as each of the limitations in an independent claim is necessarily part of the dependent claims.

91. The SoloStar® device does not have "direct gearing" (*i.e.* a "gearbox") as required in each of the asserted claims. The SoloStar® device has no gear wheels, no racks nor any other components that could be construed as a "gearbox" or "transmission" as defined by the 278 Patent. Also, during dose setting there is no "nut" that is screwed up the threads at the distal end of the lead screw. Indeed, the threads at the distal end of the lead screw in the SoloStar® device are not involved in dose setting at all. Consequently, there is no pitch ratio between the lead screw and the number sleeve that must be compensated for as required in the Novo 278 Patent. At least for these reasons, the SoloStar® device does not have the "dose setting" function as required by the asserted claims. Likewise, the SoloStar® device does not have the "injecting" ("injection" or "administration") function as required by the asserted claims.

92. The SoloStar® device also does not have a non-rotatable piston rod with a non-circular cross-section. In fact, the SoloStar® lead screw is circular in cross section and must necessarily rotate during injection otherwise the device would fail to function. This rotation of the SoloStar® lead screw is completely opposite the objectives that Novo's inventor specified for the device claimed in the 278 Patent. As discussed above, Novo's inventor, in distinguishing over the prior art, required that his claimed device should avoid transformations of linear movement to rotational movement and vice versa. Indeed, Novo's inventor recognized that such transformation of linear movement to rotational movement (and vice versa) was well known and part of the prior art devices. In contrast, the SoloStar® device practices the prior art when it transforms linear motion of the drive sleeve to rotation of the lead screw during injection. This is further confirmation that the SoloStar® device does not have the "injecting" function of the claims of the 278 patent.

93. The SoloStar® device also does not have a "clutch" as that term is properly construed. Although the SoloStar® documents label one part as the "clutch," this part is significantly different from the single structure disclosed in the 278 Patent. The SoloStar® clutch is a separate structure whereas the 278 Patent requires that the "clutch" comprise two complementary components and

most importantly have one component integral to the "dose dialing sleeve" and the other complementary component integral to the "drive sleeve." In the SoloStar® device there is no component of the clutch integral to the drive sleeve.

94. Because the SoloStar® device is missing many of the claimed elements of the 278 Patent, there can be no literal infringement. Moreover, because the differences in structure and function between the SoloStar® device and the claimed device are so significant, there can be no infringement under the Doctrine of Equivalents.[11]

**F. The Novo 278 Patent Is Invalid**

95. I have also been asked to consider the validity of the asserted claims of the 278 Patent in the event that claims are construed as Novo proposes through its witness, Mr. Clemens. *See* Clemens Affidavit, Exhibit D2. In sum, the claim construction proposed by Mr. Clemens is incomplete and incorrect. First, Mr. Clemens ignores the fact the Novo inventor significantly limited his claimed device by distinguishing it from the known prior art. *See, e.g.*, the 278 Patent, Col. 1, Lines 22-68 - Col. 2, Lines 1-42. Second, Mr. Clemens does not acknowledge the inventor's stated objectives for the structure and function of the claimed device. Col. 2, Lines 43-49. And finally, Mr. Clemens fails to take into consideration that only a single design approach is described for "dose setting" and "injecting," both of which necessarily require the use of "direct gearing," a "piston rod" that is non-rotatable and non-circular, and a "clutch" where one component is integral to the drive sleeve and the complementary component is integral to the dose dial sleeve.

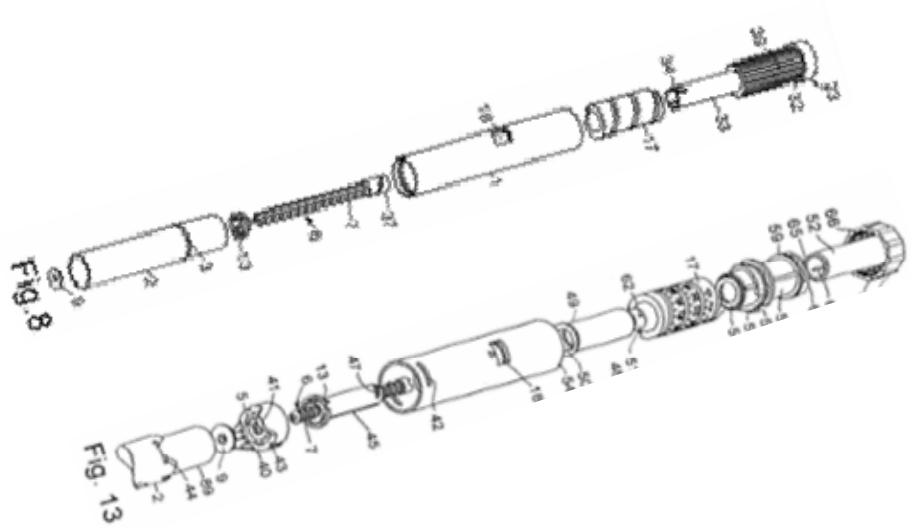
96. Using the claim construction proposed by Mr. Clemens, the asserted claims of the 278 Patent are invalid as anticipated by a number of prior art publications. There are also a number of publications that invalidate the asserted claims because they would have been obvious to one skilled in the art at the time of the invention, which at this point in my analysis I assume to be June 2000. I understand that s-a may challenge this date as incorrect. If, as a consequence of that challenge, the

[11] I note that Novo's technical expert Clemens only addresses infringement under a literal infringement analysis and not under a doctrine of equivalents analysis.

priority date becomes the filing date of the application that led to the 278 Patent, then years of additional prior art become relevant and I reserve the right to supplement this declaration at a later date.

97. The following is a list of prior publications that anticipate one or more of the asserted claims of the 278 Patent thus rendering them invalid. At a minimum, these prior art references invalidate one or more claims as obvious. Detailed claim charts are appended to this declaration as Exhibits B1-B8.

98. WO 99/38554 (Steenfeldt-Jensen) – This prior art reference was publicly available at least as early as August 5, 1999 and was filed by Novo Nordisk A/S. In particular, there are two embodiments described in this reference that invalidates every asserted claim. Detailed claim charts are in Exhibits B1 and B2.



99. U.S. Patent No. 6,248,095 (Giambattista et al.) – This patent was filed on February 23, 1998 and issued on June 19, 2001. The teachings in this patent invalidate all asserted claims of the 278 Patent. Detailed claim charts are attached as Exhibit B3.

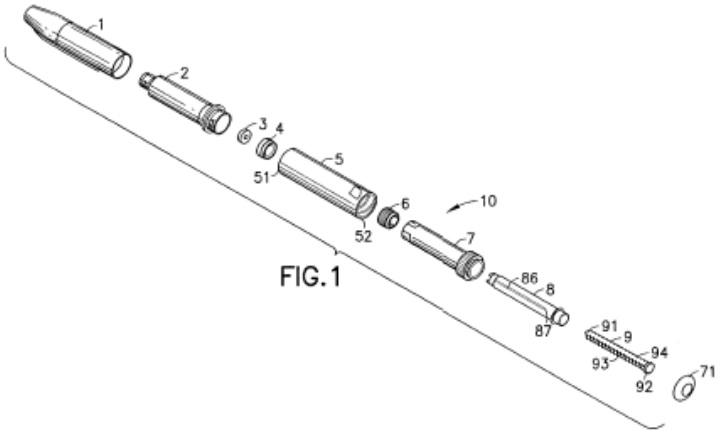
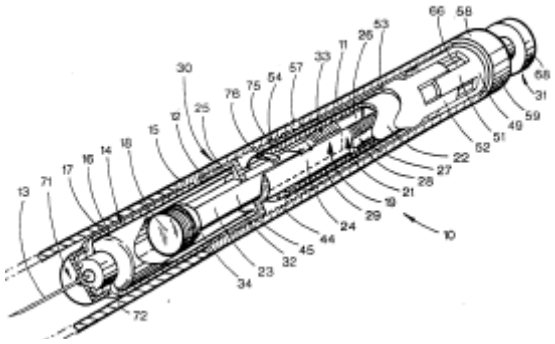


FIG. 1

100. U.S. Pat. 5,304,152 (Sams) – This patent was issued on April 19, 1994 and invalidates all claims of the 278 Patent. After reviewing the Sams 152 Patent, I was provided a copy of the Declaration of Bernard Sams. (Exhibit D6). Mr. Sams' description of the operation of the Sams 152 Patent is consistent with my understanding as set forth in the attached claim charts. Claim charts are included as Exhibit B4.



101. U.S. Patent 5,320,609 (Haber et al.) – This patent issued on June 14, 1994. Detailed claim charts are attached as Exhibit B5.

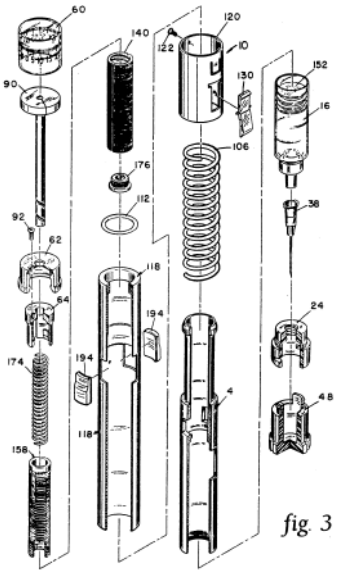
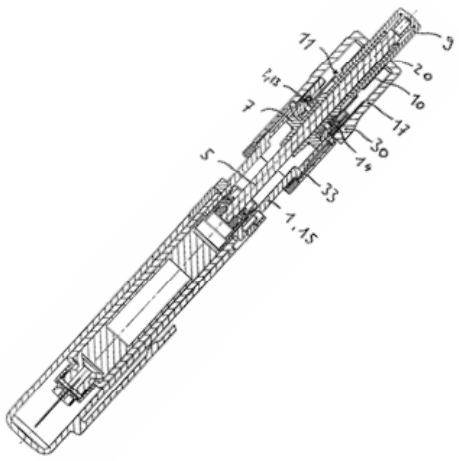
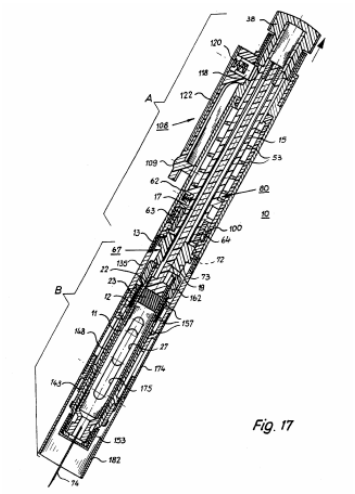



fig. 3

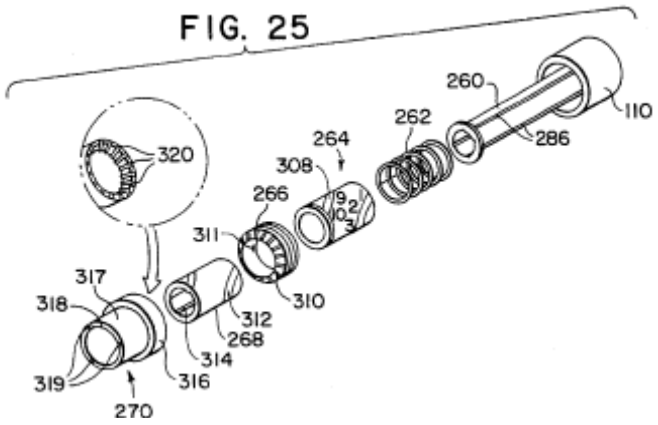
102. U.S. Patent 6,193,698 (Kirchhofer et al.) – This patent issued on February 27, 2001. Detailed claim charts are attached as Exhibit B6.




103. U.S. Patent No. 5,480,387 (Gabriel et al.) – This patent was filed by Medico Development Investment Co. and was available to the public when it issued in January, 1996. Detailed claim charts are attached as Exhibit B7.




104. U.S. Patent 5,505,704 (Pawelka et al.) – This patent issued on December 17, 1996. Detailed claim charts attached as Exhibit B8.




105. Claims 1 and 7-26 are invalid for failure to meet the enablement requirement. The 278 Patent does not teach one of ordinary skill in the art how to make and use the claimed invention as construed by Novo as set forth by Mr. Clemens. The specification of the 278 Patent discloses only the use of a gearbox for allowing the dose setting and injecting function.

106. Claims 1 and 7-26 are invalid for failure to meet the written description requirement. The 278 Patent does not describe the claimed device as construed by Mr. Clemens in sufficient detail

such that one skilled in the art can clearly conclude that the inventor was in possession of the invention as of the filing date of the original application. The written description of the 278 Patent is limited in the embodiments disclosed and is not commensurate with the scope of the asserted claims as set forth by Mr. Clemens.

### G. The Undisclosed Patents And Other Information Are Highly Material

107. Novo cited various patents and other references during the prosecution of the 278 Patent application, ***but did not cite*** certain highly material information concerning Bernard Sams prior inventions and did not cite to publications that were actually ***owned by Novo***.

108. As mentioned above, I have had the opportunity to review a declaration prepared by Bernard Sams. (Exhibit D6). I was particularly interested in paragraphs 22-29 of his declaration where he describes his working relationship with Novo circa 1986 through 1995. In early 1995, Mr. Sams approached Novo with the concepts set forth in the Sams 152 Patent and in his MA (mechanical advantage) Pen as set forth in WO 96/26754 (Application No. 9503969.9). Novo expressed interest in his MA Pen design and requested that Mr. Sams continue to provide Novo with a "proof of concept," which Mr. Sams did and for which Novo paid his design costs. This proof of concept included providing Novo with working examples of the MA Pen, including the mechanical advantage model shown in the photograph attached as an exhibit to his declaration and as shown in the movie I was provided (STR-SAMS0000847).

109. Throughout 1996, Mr. Sams continued to meet with and show Novo his design work on the MA Pen. The slide presentation that Mr. Sams presented to Novo in June of 1995 is of particular note because it illustrates that Mr. Sams told Novo about the use of (1) mechanical advantage, (2) dose limiting mechanisms, and (2) reduced injection force in pen-type injection devices. These are the same concepts that Novo has alleged it invented and described in the 278 Patent, the application of which of course it did not file until September 22, 2003. (*see* Novo's

Preliminary Injunction papers). In late 1996 Novo informed Mr. Sams that it was no longer interested in his designs.

110. As I understand the law of derivation, Novo is not the inventor of the concepts it claims. Instead, Bernard Sams is the true inventor and therefore the 278 Patent is invalid. Further, the information that Mr. Sams provided to Novo circa 1995-1996 was highly material and should have been disclosed to the Examiners of the parent patent application and the continuation application that ultimately issued as the 278 Patent.

111. In the Background section of the first filed parent patent application (09/882,536) that lead to the issuance of the 602 Patent (which also appears in the Background section of the 278 Patent), Novo's inventor distinguished well known prior pen-type injection devices from the device he was claiming by relying on direct gearing, *i.e.*, the gearbox. This distinction was entirely consistent with the originally filed claims in that parent patent application because each claim specifically set forth direct gearing. Likewise, the claims that ultimately issued in the parent 602 Patent each recited direct gearing, again consistent with what Novo's inventor stated as the objective of his invention when he first filed his application in the U.S. in 2001.

112. In 2003 Novo filed the continuation application (10/667,040) that ultimately issued as the 278 Patent using the identical specification as the parent application. The originally filed claims in that 10/667,040 application once again specifically recited direct gearing. Then, 3 ½ years later, Novo amended the originally filed claims and added one new claim (claim 13) that omitted the specific recitation of direct gearing. Nowhere in the file history does Novo inform the Examiner of this omission. Likewise, Novo did not explain the inconsistency that this caused with regard to the distinctions Novo's inventor originally made in the Background section of the application. This added claim was a material change to the prosecution of the application and Novo should have informed the Examiner of the inconsistency it created.

113. Novo also did not tell the Examiner about its own publications, specifically WO 90/09202 (Ejlersen – Novo Nordisk A/S), which was published on August 23, 1990, and WO 91/10460 (Bonnichsen – Novo Nordisk A/S), which was published on July 25, 1991 (also published as European Patent Specification No. EP 0 513 128 B1 on July 19, 1995). Exhibits D3 and D4.

114. As discussed in detail below, these two Novo references each establish, at a minimum, a *prima facie* case of unpatentability of at least independent Claims 1 and 12.

115. Novo's 90/09202 application discloses an injection pen with numerous claimed elements of the 278 Patent, including many, if not all, of the elements recited in at least Claims 1 and 12. As such, the non-cited Novo 90/09202 application is highly material to the patentability of the Novo 278 Patent.

116. Specifically, the Novo 90/09202 application discloses at least a piston rod having a threaded portion ("piston rod compris[ing] an outer part 12" and "a screw part 13"), a housing ("guide piece 17")(*See* e.g., Exhibit D3, Page 10; Fig. 3), a dose dial sleeve threadedly engaged with a portion of the device ("a drum 25 . . . whose cross-sectional shape corresponds to that of the pin 19 and in which the pin 19 can be inserted and secured in a mechanical connection that is fixed with respect to turning," wherein "pin 19 is fixedly connected to the screw part 13," (*See, e.g.*, Exhibit D3 Pages 8-9), and a drive sleeve ("pin 19"; "screw part 13")(Fig. 3).

117. Novo's 90/09202 application additionally discloses that the dose dial sleeve and the drive sleeve are releasably coupled together ("[i]n the end of the jacket there has been inserted a bottom piece 27 having a pin 28 . . . where the pin 28 protrudes in order to act upon the pin 19 during the pressing-in of the jacket during the injection," (*See, e.g.,* Exhibit D3 Page. 9).

118. Novo's 90/09202 application also discloses that during the dose setting operation the dose dial sleeve and the drive sleeve are coupled so that they rotate together ("a drum 25 . . . whose cross-sectional shape corresponds to that of the pin 19 and in which the pin 19 can be inserted and secured in a mechanical connection that is fixed with respect to turning" such that "while the drum

25 is in engagement with the pin 19[,] . . . preadjustment can take place by turning the drum," (*See, e.g.,* Exhibit D3 Pages 9 and 13).

119. Novo's 90/09202 application further discloses that during injection, the dose dial sleeve is decoupled from the drive sleeve so that the drive sleeve does not rotate during injecting and instead moves in a longitudinal direction ("the pin 28 protrudes in order to act upon the pin 19 during the pressing-in of the jacket during the injection") (*See, e.g.,* Exhibit D3 Page 9).

120. The second highly material reference not disclosed by Novo is their WO 91/10460 patent specification. It describes an apparatus for mixing and injecting a medicine as well as numerous claimed elements of the 278 Patent, including many, if not all, of the elements recited in at least Claims 1 and 12.

121. Novo's 91/10460 application discloses at least a piston rod having a threaded portion ("piston rod 9"), a housing ("house 17"), a rotatable dose dial sleeve ("scale 7"), and a drive sleeve ("cap 10, 20") (*See, e.g.,* Exhibit D4 Fig. 1).

122. Novo's 91/10460 application also discloses that during the dose setting operation the dose dial sleeve and the drive sleeve are coupled so that they rotate together ("the cap 10 engages the scale 7 and a presetting may be performed by rotating the cap relative to the piston rod 9") (*See, e.g.,* Exhibit D4 Page 7).

123. Novo's 91/10460 application further discloses that during injection, the dose dial sleeve is decoupled from the drive sleeve so that it rotates back to an original pre-dose setting position upon completion of the injection, but the drive sleeve does not rotate during injecting and instead moves in a longitudinal direction ("the cap 10 will be out of engagement with the scale 7 which is set to zero by the spring 12" and "the injection is [then] performed by pressing the cap 10 against the case 8").

124. Novo did not disclose these highly material references during prosecution of the 278 Patent, while at the same time disclosing other international applications on which Novo is named,

including International Publication No. WO 99/38554 (Steenfeldt-Jensen), which was published on August 5, 1999, and International Publication No. WO 98/57688 (Klitmose et al.), which was published on December 23, 1998.

125. Because Novo failed to cite these two references to the Patent Office, Novo's 90/09202 application and Novo's 91/10460 specification were not considered by the 278 Examiner. In the Examiner's statement of reasons for allowance, the Examiner stated the following:

> The prior art made of record did not disclose or suggest a drug delivery device that includes all of the limitations recited in independent clams 13, 22, 36, 40, 47, and 50. Specifically, the prior art did not disclose or suggest a dose dial sleeve (called dose setting drum in clam 40) and a drive sleeve (called tubular element in claim 40) that are releasably coupled together so that these elements rotate together in a dose setting operation to set a dose and decouple [*sic*] from each other in an injection operation allowing the dose dial sleeve to rotate and the drive sleeve to move in a longitudinal direction toward the injection end.

April 23, 2007 Detailed Action Examiner's Amendment. Exhibit C12.

126. Although I disagree with this statement, these non-cited Novo references could not be cumulative since they teach the limitations that the Examiner failed to find in the references before him.

## V. Revision or Supplementation

127. To the extent that the Court may construe the asserted claims of the 278 Patent in a fashion that differs from the claim constructions applied above, my analysis may be revised or supplemented. I also reserve the right to do so to the extent new information becomes available, applicable law changes, or as otherwise permitted by the Court or the applicable rules.

## VI. Demonstrative Exhibits

128. If called to testify, I may prepare drawings or animations to illustrate the contents of this declaration.

Dated: 11-16-07

Neil Sheehan

# EXHIBIT A1

**NEIL SHEEHAN**
One Southgate Street
Atherton, CA 94027
Tel: (650) 363-0913
Fax: (650) 363-0923
E-mail: neiljs@aol.com

**Education:**

Villanova University, Villanova, PA: BS Mechanical Engineering, 1968
*Summa Cum Laude*
*Newspaper Editor-in-Chief*
*1993 Alumni Professional Achievement Award*

Harvard University, Cambridge, MA: Graduate School, 1968-1969
*Engineering and Applied Physics*
*National Science Foundation Fellow*

University of California, Berkeley, CA: Pre-Med Coursework, 1974-1975
*Organic Chemistry and Biology*

**Experience:**

1993-2007 **Consulting Engineer and Expert Witness** (1995-2007)
Independent consulting engineer specializing in medical products design and development with a focus on medium and high volume disposable devices and components. Expert witness information is available upon request. Engineering clients (in alphabetical order) have included:

| | |
|---|---|
| Arcturus (Mountain View, CA) | *Laser micro-dissection disposable elements and packaging designs.* |
| Better Care (San Francisco, CA) | *Male and female incontinence devices.* |
| Cardeon, Inc. (Huntington Beach, CA) | *Specialty cardiac catheter.* |
| Cardiometrics (Mountain View, CA) | *Diagnostic cardiac catheter components.* |
| Decibel Instruments (Hayward, CA) | *Disposable elements for innovative hearing aid system.* |

| | |
|---|---|
| Eunoe, Inc.<br>(Pleasanton, CA) | *Implantable Alzheimer's Disease devices.* |
| Fallbrook Engineering<br>(Valley Center, CA) | *Various proprietary medical devices.* |
| FemmeSource Health<br>(Pasadena, CA) | *Various gynecological diagnostic devices.* |
| Fogarty Engineering<br>(Portola Valley, CA) | *Proprietary catheter devices.* |
| Heartstream<br>(Seattle, WA) | *Multi-function defibrillator electrodes.* |
| Hexcel<br>(Pleasanton, CA) | *Proprietary materials-based device.* |
| HiLife Therapeutics<br>(So. San Francisco, CA) | *Lens enhancements for patient communications systems.* |
| Inviro Medical Devices<br>(Vancouver, BC) | *Innovative safety syringes.* |
| IPT, Inc.<br>(Palo Alto, CA) | *Umbilical cord blood sampler/clamp.* |
| Katecho, Inc.<br>(Des Moines, IA) | *Multi-function defibrillator electrodes and other proprietary devices.* |
| KippGroup<br>(Ontario, CA) | *Proprietary IV-related device.* |
| Lucent Medical<br>(Bellevue, WA) | *Endoscopic tool containment systems.* |
| Mallinckrodt / Nellcor<br>(Pleasanton, CA) | *Pulse oximetry sensors.* |
| Mayfield Fund<br>(Menlo Park, CA) | *Medical technology evaluations.* |
| McGaw, Inc.<br>(Irvine, CA) | *Cannula-based needle-less injection sites for IV administration.* |
| Medasonics<br>(Fremont, CA) | *Transcranial ultrasonic (Doppler) probe mounting systems.* |

| | |
|---|---|
| Medisystems<br>(Seattle, WA) | *Hemodialysis bloodline components.* |
| Medtronic CardioRhythm<br>(San Jose, CA) | *Cardiac ablation catheter systems.* |
| Minimus Surgical<br>(SF and Atherton, CA) | *Proprietary obesity surgery devices. (Founder)* |
| Natus Medical<br>(San Carlos, CA) | *Advanced ear couplers and electrodes for newborn hearing screener.* |
| Nexan<br>(Cambridge, UK) | *Proprietary multi-function electrode systems.* |
| Pneumation<br>(Evergreen, CO) | *CPAP (Continuous Positive Airway Pressure) system for sleep apnea.* |
| R&D Medical<br>(Lake Forest, CA) | *Various high-volume disposables including complex electrode systems.* |
| Rhaphis Medical<br>(Sunnyvale, CA) | *Semi-automatic surgical suturing device for the third world.* |
| Starion<br>(Palo Alto, CA) | *Proprietary electrosurgery device.* |
| Target Therapeutics<br>(Fremont, CA) | *Packaging and delivery system for cranial catheter/coil occlusion device.* |
| Woodside Biomedical<br>(Carlsbad, CA) | *Proprietary nerve stimulation electrode designs (disposable and reusable).* |

1989-1992 **Natus Medical Inc.**, Foster City, CA
Vice President, Engineering and Manufacturing
Medical electronics and disposables for neonates.
*Start-up. Created and managed engineering, manufacturing, documentation, quality assurance, materials, clinical testing, customer and technical service. Established comprehensive vendor network. Thirty-five employees.*

1987-1989 **Nellcor Incorporated**, Hayward, CA
Manager, Disposables Engineering
Pulse oximetry and capnography.
*Design, management of small staff, clinical research, marketing aids, national sales meeting presenter.*

1986-1992 **Medisystems Corporation**, San Francisco, CA
Consultant
Hemodialysis blood tubing sets and related components.
*Individual contributor.*

1986-1987 **Critikon, Inc.**, San Jose, CA
Senior Mechanical Engineer
Intravenous delivery systems and sets.
*Coordination of San Jose, Tampa and Japan Medical Supply.*

1985-1986 **Raychem Corp. / Menlo Care Inc.**, Menlo Park, CA
Consultant
Intravenous catheters and systems.
*Individual contributor.*

1984-1985 **American Hospital Supply Corp.**, Emeryville, CA
Senior Project Engineer
Liquid handling systems, especially pipettors.
*Individual contributor, liaison during transfer to American Dade.*

1982-1983 **Liquid Bracelet Company**, Berkeley, CA
Sole Proprietor
Liquid-filled (IV tubing) fashion jewelry ($250,000 in sales).
*Design, manufacturing, marketing, sales and public relations.*

1975-1982 **Cutter Laboratories**, Berkeley, CA
Product Development Engineer
Intravenous delivery systems and components.
*Individual contributor, liaison to other plants.*

1969-1973 **Magnetic Head Corporation**, Hauppauge, NY
Design Engineering Supervisor
Magnetic tape heads for computer peripherals.
*Created department, documentation and MRB systems.*

1965-1967 **Tangent Machine and Tool Corp.**, Farmingdale, NY
Summers Tool Designer/Drafter and Machine Operator

---

**Product designs, inventions and patents (partial list):**

---

**Consultant**

Innovative surgical devices and methods (Minimus)
*Device implantation, obesity applications, fastener systems*
**Patent No. 7,255,675 (August 14, 2007)**